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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,665

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EXAMINER

MCCORMICK, MELENIE LEE

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,665	Applicant(s) MOON ET AL.	
	Examiner MELENIE MCCORMICK	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-10 and 14-28 is/are pending in the application.
- 4a) Of the above claim(s) 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-10, 14-18 and 23-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' remarks with claim amendments received 14 September 2008 have been received and considered.

Claims 1-3, 7-8 and 11-13 have been cancelled.

New claims 14-28 have been added.

Claims 4-10 and 14-28 are pending.

Claims 19-22 are withdrawn as being drawn to a non-elected invention. The previously examined claims were drawn to a method of making a grape seed extract and to a grape seed extract containing composition. New claims 19-22 are drawn to a method of administering to treat a mammal. This is different from the method of making an extract and the composition comprising an extract which was previously examined. The method of treatment requires an administration step which is not required of the inventions previously examined.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 19-22 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 4-10, 14-18, and 23-28 are presented for examination on the merits.

Withdrawn Rejections

The previous rejection under 35 U.S.C. 112, first paragraph has been withdrawn in light of the amendments to the claims, which are no longer drawn to a composition for treatment and prevention of any and all brain diseases caused by degeneration and have now been amended to recite a composition for the treatment of ischemic brain disease.

The previous rejection under 35 U.S.C. 112, second paragraph has been withdrawn in light of Applicants' arguments regarding the phrase 'sitologically acceptable additive', as meaning a substance which becomes a component of or affects the characteristics of a food.

The previous rejection under 35 U.S.C. 102(b) over Sekimoto has been withdrawn in light of the amendments to the composition claims, which are now all product by process claims.

Maintained Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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Claims 4-6 stand rejected under 35 U.S.C. 102(a) as being anticipated by Kim et al. (KR20040052398). New Claims 14-18, 24, and 26-28 are also rejected under 35 U.S.C. 102(a) as being anticipated by Kim et al. (KR20040052398) for the reasons set forth below.

Kim et al. teach a method of preparing a grape seed extract. Kim et al. teach that the grape seed is extracted with water at pH 8-11 (alkaline pH). Kim et al. also teaches that the mixture is centrifuged after the pH is adjusted to pH 2-4. Kim et al. further teaches that a precipitate is collected and re-suspended in alcohol, then centrifuged and that hexane (a non-polar solvent) is then added and removed, that the product is refined (which reads on further purification) and that the extract is then freeze-dried (see e.g. English translation- Claim 1). Kim et al. also teach that in addition to water, methanol or ethanol can be used as the solvents (see e.g. claim 4). Kim et al. further teach that the extract is used in a pharmaceutical composition and in a health food with acceptable additives (see e.g. claims 6 and 8).

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6, 9-10, 15-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Sekimoto (JP 11302142).

Sekimoto discloses a grape extract composition which appears to be identical to the presently claimed extract composition. Sekimoto teaches a food composition which comprises a grape seed extract (see e.g. claim 2). Sekimoto also discloses a candy which comprises grape seed extract and vitamin C (which reads on an additive). This candy composition reads on the instantly claimed health food comprising grape seed extract with a sitologically acceptable additive. Sekimoto also teaches a solid pharmaceutical form including a tablet or capsule which contains grape seed extract (see e.g. [0036]). Sekimoto also teaches that the grape seed can be extracted using lower alcohols, water or a combination of the two as the solvent (see e.g. [0029]). Sekimoto also teaches that the grape seed extract comprises 10 to 50% by weight of the composition (see e.g. [0035]), which is within the range instantly claimed. Although Sekimoto does not teach that the composition can be used in the manner instantly claimed (as a treatment for brain degenerative disorders), the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the

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intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Sekimoto also disclose that the grape seed extract was prepared using water as a solvent (see e.g. [0029]). Sekimoto also teaches that the extract can be further purified using well-known methods (see e.g. [0031]) and that the extract is used in dry form (see e.g. [0032]). Even if the exact method of preparing the extract is not identical to the method instantly claimed, a person of ordinary skill in the art would reasonably expect that a grape seed extract could be produced using the commonly employed and well known techniques of aqueous alkaline extraction followed by acid neutralization, centrifugation followed by re-suspension and repeated purification followed by drying. This is especially true given the disclosure of Sekimoto that the grape seed extract can be condensed further or may be refined and further purified (see e.g. [0031]). Therefore, a person of ordinary skill in the art would be motivated to perform commonly employed purification steps and repeat them as necessary in order to obtain a dry grape seed extract as taught by Sekimoto (see e.g. [0032]) and instantly claimed. The term 'alkaline' water is given the broadest reasonable interpretation, which means it can be even slightly above pH 7. Therefore, the use of 'alkaline' water would not materially change the composition.

With respect to the USC 102/103 rejection above, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' grape seed extract composition differs and, if so, to what extent,

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from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

New Rejections

Claim Objections

New Claims 16 and 17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 16 and 17 merely recite an intended use for the composition of claim 15, but do not limit the composition itself.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 23 recites "The method of claim 14, further comprising; between steps j and k, the additional steps of

1. adding the non-polar solvent to the non-polar solvent layer collected in step j and mixing solution, and
2. collecting non-polar layer."

Support for this claim cannot be found in the specification as originally filed. It is therefore not clear that Applicants were in possession of the method of claim 23 at the time the application was filed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6 , 9-10, 14-18, and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (KR20040052398).

Kim et al. beneficially teach a grape seed extract composition and a method of preparing a grape seed extract is relied upon for the reasons set forth above. Kim et al. also teach that a composition comprising the grape seed extract comprises 0.1% to 50% by weight of the grape seed extract and that grape seed extract is the active ingredient for treating diabetes (see page 5, para 32-33).

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Kim et al. does not explicitly teach that distilled water is used as the solvent or that the grape seed extract is present in the composition in an amount ranging from 0.01 to 80% by weight or 1 to 50% by weight.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use distilled water as the extraction solvent. Kim et al. teach that water is used, therefore a person of ordinary skill in the art would have reasonably understood that using more purified water, such as distilled water, would have been advantageous in a method of preparing an edible composition. It would have further been obvious to one of ordinary skill in the art to optimize the amount of the grape seed extract in the composition since Kim et al. teach that it may be present in an amount from 0.1% to 50% by and that grape seed extract is the active ingredient for treating diabetes (see page 5, para 32-33). Therefore, a person of ordinary skill in the art would have been motivated to adjust the amount of the grape seed extract to optimize the therapeutic effect of the composition.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

This new rejection under 35 U.S.C. 103(a) is necessitated by amendment. The previous claims did not recite 'distilled water'. In addition, the previous claims reciting particular limitations with regards to the amount of the grape seed extract present in the

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composition claimed (old claims 9 and 10) were not product by process claims and were drawn to a health food comprising any grape seed extract and an additive.

Response to Arguments

102/103 over Sekimoto

Applicants have separately addressed this rejection under 35 U.S.C. 102 and 35 U.S.C 103. Please note that the rejection under 35 U.S.C. 102 has been withdrawn. The current rejection is a 102/103 rejection.

Applicants have cited MPEP 2113, which states that "even though product- by - process claims are limited by the and defined by the process, determination of patentability is based upon the product itself". Applicants argue that the process described in Sekimoto has major and significant differences from the process in claim 15, and that the end product obtained by Sekimoto is not the same as the product by the process of claim 15. Applicants have explained that the product of claim 15 is an extract and reviewed various extraction methods, including some of those described in the background of Sekimoto. Applicants argue that Sekimoto, not any of the cited "well known approaches" disclose a process of extraction such as that claimed in the method of claim 14. This reasoning, however, is not persuasive. Although Sekimoto does not disclose each of the particular method steps claimed, Sekimoto is not relied upon for the disclosure of a method for extracting a grape seed extract. Rather, Sekimoto teaches a grape seed extract composition. As previously stated, the Patent and Trademark Office

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is not equipped to conduct experimentation in order to determine whether Applicants' grape seed extract composition differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants. Applicants have not provided any evidence regarding particular characteristics or components of the instantly claimed grape seed extract which would necessarily distinguish it from the extract taught by Sekimoto. Applicants have explained how certain method steps (i.e. extraction with solvents of different polarities) could produce a composition with different components or different amounts of particular components compared to an extract prepared by an alternative method. However, Applicants have not particularly pointed to any such unique components or unique amounts of components which would distinguish the instantly claimed composition over the composition in the instantly cited prior art.

The rejection is therefore deemed proper and is maintained.

102(a) over Kim et al.

Applicants argue that an English translation of the priority document Korean Patent Application KR 20030078503 has been submitted with this response. Applicants further argue that the Kim et al. reference has a publication date after the priority date of the present application. This is not found persuasive. The English translation submitted by Applicants was submitted on 18 January 2008. This translation, however, is not accepted for providing Applicants benefit of priority to KR 20030078503 because the

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translation submitted is not a certified translation. Please see MPEP 2304.01(c) .

Translation of Foreign Benefit Application :

A certified translation of every foreign benefit application or Patent Cooperation Treaty (PCT) application not filed in English is required. 35 U.S.C. 119(b)(3) and 372(b)(3) and 37 CFR 1.55(a)(4). If no certified translation is in the official record for the application, the examiner must require the applicant to file a certified translation. The applicant should provide the required translation if applicant wants the application to be accorded benefit of the non-English language application. Any showing of priority that relies on a non-English language application is prima facie insufficient if no certified translation of the application is on file. 37 CFR 41.154(b) and 41.202(e).

Applicants' effective filing date is there 02 November 2004 and Kim et al. is a prior art reference under 35 U.S.C. 102(a).

The rejection is therefore deemed proper and is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELENIE MCCORMICK whose telephone number is (571)272-8037. The examiner can normally be reached on M-F 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Patricia Leith/
Primary Examiner, Art Unit 1655